

**EPA REGISTRATION NUMBER 35935-77 – Vol. 1**

ISB'S Front-end PRIA Completeness Screen  
Draft 3; 10/25/07

EPA Receipt Date: <b>AUG - 4 2009</b>		EPA Reg. Number: <b>35935-TT</b>		
	Check List Item	Yes	No	N/A
1	Has the <b>PRIA Fee been Paid</b> ; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an <b>Application Form</b> (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a <b>Confidential Statement of Formula</b> (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a <b>Formulator's Exemption Statement</b> (EPA Form 8570-27) Included in the Submission Package?			
5	Is a <b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) Included in the Submission Package?			
6	Is a <b>Data Matrix</b> (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a <b>Label</b> Included in the Submission Package?	X		
8	Are <b>Data</b> Included in the Submission Package?	X		
9	<b>Is the Submission an Amendment?</b>		X	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

Mr. Nathan P. Ehresman  
Nufarm Limited  
4020 Aerial Center Pkwy., Ste 101  
Morrisville, NC 27560

NOV 26 2012

Subject: Conditional Data: Storage Stability and Corrosion Characteristics  
Product Name: Fluroxypyr Technical (II)  
EPA Reg. No: 35935-77

Dear Mr. Ehresman:

The storage stability and corrosion characteristics data for the product referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), are acceptable. These conditional data requirements for registration are now fulfilled.

Guideline #	Study Type	MRID #	Study Classification
830.6317	Storage Stability	48124101	Acceptable
830.6320	Corrosion Characteristics		

If you have questions or concerns regarding this letter, please contact Beth Benbow at (703) 347-8072 or email at [benbow.bethany@epa.gov](mailto:benbow.bethany@epa.gov).

Sincerely,

*Beth Benbow*

*for*

Kathryn V. Montague  
Product Manager 23  
Herbicide Branch  
Registration Division (7505P)





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**DATE OUT:** September 24, 2012

**SUBJECT:** Storage Stability and Corrosion Study - Product Chemistry Review

**FROM:** Bruce Kitchens / Shyam Mathur  
Product Chemistry Team  
Technical Review Branch / Registration Division (7505P)

*Bruce Kitchens*  
*SBM 9/24/12*

**TO:** Juanita Gilchrist / Kable Davis  
Dianne Morgan / Kathryn Montague  
Michael Walsh / Kathryn Montague  
Bethany Benbow / Kathryn Montague  
Jasmine Branch / Kathryn Montague  
Registration Division (7505P)

**Company Name / Number:** NUFARM LIMITED / 35935

**INTRODUCTION:**

In support of previous applications, the company / applicant has submitted the one year Storage Stability and Corrosion Characteristics studies for the following products:

PM	Reg. No.	DP Barcode	Decision No.	MRID No.	PC Code
25	35935-71	372655	424740	479282-01	129008
23	35935-74	380729	436924	481247-01	128968
23	35935-76	376116	431009	480351-01	110201
23	35935-77	380642	436922	481241-01	128968
23	35935-95	404224	468095	488730-01	129092



**SUMMARY OF FINDINGS:**

The Technical Review Branch has performed a fast track review of the associated products and concludes all of the studies are "acceptable". No products exhibited degradation of the active ingredient(s) in the products or corrosion of the packing material were observed during the period of testing.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 22, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

NUFARM LIMITED  
PO Box 13439  
RTP, NC 27709-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 17-JUN-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# Receipt for Section 3

S: 876694

Resubmission: ☒ Yes ☐ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☐ Yes ☒ No

Company: 35935 NUFARM LIMITED

V

Risk Manager: Registration Division, Risk Management Team 23

Product #: 35935-77

Product Name: FLUROXYPYR TECHNICAL (II)

Override#:

Me Too  
Section3: 62719-285

Me Too  
Product Name: STARANE F TECHNICAL

Application Date: 15-Jun-2010



OPP Rec'd Date: 17-Jun-2010



Front End Date: 17-Jun-2010



Risk Manager Send Date: 17-Jun-2010



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

storage stability and corrosion characteristics per Agency letter of 2/19/10

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit





Nufarm Limited **481241-00**  
George Meindl  
Regulatory Affairs Manager  
150 Harvester Drive, Suite 200  
Burr Ridge, IL 60527  
Phone: 630.455.2017 Fax: 630.455.2030  
[george.meindl@us.nufarm.com](mailto:george.meindl@us.nufarm.com)

June 15, 2010

Via Overnight Courier

Kathryn Montague (PM-23)  
Document Processing Desk  
Office of Pesticide Programs (7505P)  
U. S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Subject: Fluroxypyr Technical (II)  
EPA Reg. No. 35935-77  
Submission of storage stability and corrosion characteristics per  
Agency letter dated February 19, 2010

Dear Ms. Montague:

Enclosed please find three (3) copies of the storage stability, including corrosion characteristics for the subject product registration as requested in the EPA dated February 19, 2010.

To process this request please find enclosed the following:

- Application for Pesticide Registration (EPA form 8570-1)
- **48124101** Storage stability (OPPTS Guideline Series 830.6317) and Corrosion characteristics (OPPTS Guideline Series 830.6320) for the subject product (3 copies)

If you should have any questions regarding this matter, please feel free to contact me at 630.455.2017 or email at [george.meindl@us.nufarm.com](mailto:george.meindl@us.nufarm.com).

Sincerely,

A handwritten signature in black ink, appearing to read 'George Meindl', written over a horizontal line.

George Meindl  
Regulatory Affairs Manager  
Nufarm Limited

35935-77

SS/CC

Cond.  
data

## Memorandum

Date: 06 / 27 / 10

To: PT 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 35935-77	2. EPA Product Manager Kathryn Montague	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Fluroxypyr Technical (II)	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Nufarm Limited 150 Harvester Drive Suite 200 Burr Ridge, IL 60527 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of storage stability (830.6317) and corrosion characteristics (830.6320) data as requested in Agency letter dated 2/19/2010

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name George Meindl george.meindl@us.nufarm.com		Title Regulatory Affairs Manager	
		Telephone No. (Include Area Code) 630.455.2017	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature		3. Title Regulatory Affairs Manager	
4. Typed Name George Meindl		5. Date 6/15/2010	



# Administrative Materials



Nufarm Limited  
George Meindl  
Regulatory Affairs Manager  
150 Harvester Drive, Suite 200  
Burr Ridge, IL 60527  
Phone: 630.455.2017 Fax: 630.455.2030  
[george.meindl@us.nufarm.com](mailto:george.meindl@us.nufarm.com)

April 26, 2010

Via Overnight Courier

Kathryn Montague (PM-23)  
Document Processing Desk (FIN LABEL)  
Office of Pesticide Programs (7505P)  
U. S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Subject: Fluroxypyr Technical (II)  
EPA Reg. No. 35935-77  
Final Printed label

Dear Ms. Montague:

Enclosed are the subject product's final print labeling, which is now consistent with the EPA comment letter and EPA stamped label dated 2/19/2010.

To process this request please find enclosed the following:

- Application for Pesticide Registration (EPA form 8570-1)
- Final print labeling (1 copy)

If you should have any questions regarding this matter, please feel free to contact me at 630.455.2017 or email at [george.meindl@us.nufarm.com](mailto:george.meindl@us.nufarm.com).

Sincerely,

A handwritten signature in black ink, appearing to read 'George Meindl', is written over a faint, larger version of the same signature.

George Meindl  
Regulatory Affairs Manager  
Nufarm Limited



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 35935-77	2. EPA Product Manager Kathryn Montague	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Fluroxypyr Technical (II)	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Nufarm Limited 104 T.W. Alexander Drive (PO Box 13439) RTP, NC 27709  <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 2/19/2010
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

### Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name George Meindl george.meindl@us.nufarm.com	Title Regulatory Affairs Manager	Telephone No. (Include Area Code) 630.455.2017
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Manager	
4. Typed Name George Meindl	5. Date 4/26/2010	



#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product is for manufacturing use only and is intended for formulation into end use products for:

Crops, including barley, wheat and oats, field corn, sweet corn, onions (dry bulb), pome fruit, sorghum, and grasses grown for seed.

Fallow cropland

Non-cropland, including rangeland, permanent pastures and pine plantations

Turf

All other uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.

Uses for experimental purposes that are in compliance with EPA requirements.

Detailed information on chemical and physical properties and other formulating recommendations for this product are available upon request from Nufarm. Obtain and read this information before undertaking the formulation of Fluroxypyr Technical in order to avoid formulation hazards and insure a satisfactory finished product.

Formulators using the product are responsible for obtaining EPA registration for their formulated product. Labeling for products formulated from this product must conform to that which is currently registered with the U.S. Environmental Protection Agency. For specific information on federally registered uses, contact Nufarm Americas Inc.

#### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Keep container closed when not in use. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material is spilled for any reason or cause, carefully sweep material into a pile and dispose of as directed for pesticides below.

Refer to Precautionary Statements on label for hazards associated with the handling of this material. In spill or leak incidents, keep unauthorized people away. You may contact Chemtrec (800) 424-9300.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. For metal or plastic containers, triple rinse container (or equivalent) promptly after emptying. For fiber drums, completely empty the residue into manufacturing equipment. Then (for all containers), offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration if allowed by state or local authorities.

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300  
For Medical Emergencies Only, Call (877) 325-1840

#### **WARRANTY DISCLAIMER**

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A

PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

#### **LIMITATION OF LIABILITY**

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BY WAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR ARISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

**(RV021910)**



# Fluroxypyr Technical (II)

## ACTIVE INGREDIENT:

Fluroxypyr 1-methylheptyl ester..... 98%

OTHER INGREDIENTS: ..... 2%

TOTAL ..... 100%

EPA Reg. No. 35935-77

EPA Est. No.

**KEEP OUT OF REACH OF CHILDREN**

## **CAUTION**

### **FIRST AID**

#### **IF IN EYES**

Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.  
Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.  
Call a poison control center or doctor for treatment advice.

#### **IF INHALED**

Move person to fresh air.  
If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.  
Call a poison control center or doctor for further treatment advice.

#### **IF ON SKIN OR CLOTHING**

Take off contaminated clothing.  
Rinse skin immediately with plenty of water for 15 to 20 minutes.  
Call a poison control center or doctor for treatment advice.

#### **HOT LINE NUMBER**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.  
You may also contact 1-877-325-1840 for emergency medical treatment information.

### **PRECAUTIONARY STATEMENTS**

#### **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

#### **CAUTION**

Causes moderate eye irritation. Harmful if inhaled or absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco products. Remove contaminated clothing and wash before reuse.

#### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless this product is specifically identified and addressed in an NPDES permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

**NET CONTENTS:**

**MANUFACTURED FOR  
NUFARM LTD.  
BURR RIDGE, IL 60527**



# Material to be added to an e-Jacket/Jacket

Reg. No. 35935-77

Description: New product

1. ☐ Placement within the e-Jacket/jacket:
- ☐ Default: (chronological, top = newest)
  - ☐ File Location: (PDF page number, i.e., "before page 45")

2. ☒ Send to Data Extraction contractors this material:

- ☒ Newly stamped accepted label
- ☐ Notification
- ☒ New CSF
- ☐ Other: \_\_\_\_\_

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Bethany Benbow

Phone: 347-8072 Division: RD/HAB

Date: 2/19/10

Created August 14, 2008



U.S. ENVIRONMENTAL PROTECTION  
AGENCY

Office of Pesticide Programs  
Registration Division (7505P)  
Ariel Rios Building  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

EPA Reg. Number:

35935-77

Date of Issuance:

FEB 19 2010

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Name of Pesticide Product:

Fluroxypyr Technical (II)

Name and Address of Registrant (include ZIP Code):

Nufarm Limited  
150 Harvester Drive, Suite 200  
Burr Ridge, IL 60527

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is registered in accordance with FIFRA provided that you:

1. Submit and/or cite all data required for registration review/reregistration of your product when the Agency requires all registrants of similar products to submit data.
2. Submit the data listed below:
  - a. Within one year of the date on this registration notice, Storage Stability (830.6317) and Corrosion Characteristics (830.6320) studies must be submitted. It is recommended that the observations be made at 0, 3, 6, 9, and 12 month intervals.
3. Make the following label revisions:
  - a. Replace "EPA Reg. No. 35935-xx" with "EPA Reg. No. 35935-77"
  - b. Revise "...public water..." with "...other waters..." in the first sentence of the Environmental Hazards statement.  
In addition, add "local" before "...sewage treatment plant authority."
  - c. Revise "maybe" to "may be" in the Pesticide Disposal sentence.
4. Submit one (1) copy of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Kathryn V. Montague  
Project Manager 23  
Herbicide Branch  
Registration Division (7505P)

Date:

FEB 19 2010



# Fluroxypyr Technical (II)

## ACTIVE INGREDIENT:

Fluroxypyr 1-methylheptyl ester..... 98%

OTHER INGREDIENTS: ..... 2%

TOTAL ..... 100%

EPA Reg. No. 35935-xx

EPA Est. No.

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated:**

FEB 19 2010

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under FPA Reg. No.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**FIRST AID**

35935-77

### IF IN EYES

Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice.

### IF INHALED

Move person to fresh air.

If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

Call a poison control center or doctor for further treatment advice.

### IF ON SKIN OR CLOTHING

Take off contaminated clothing.

Rinse skin immediately with plenty of water for 15 to 20 minutes.

Call a poison control center or doctor for treatment advice.

### HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.  
You may also contact 1-877-325-1840 for emergency medical treatment information.

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### CAUTION

Causes moderate eye irritation. Harmful if inhaled or absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco products. Remove contaminated clothing and wash before reuse.

### ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

NET CONTENTS:

MANUFACTURED FOR  
NUFARM LTD.  
BURR RIDGE, IL 60527



#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product is for manufacturing use only and is intended for formulation into end use products for:

Crops, including barley, wheat and oats, field corn, sweet corn, onions (dry bulb), pome fruit, sorghum, and grasses grown for seed.

Fallow cropland

Non-cropland, including rangeland, permanent pastures and pine plantations

Turf

All other uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.

Uses for experimental purposes that are in compliance with EPA requirements.

Detailed information on chemical and physical properties and other formulating recommendations for this product are available upon request from Nufarm. Obtain and read this information before undertaking the formulation of Fluroxypyr Technical in order to avoid formulation hazards and insure a satisfactory finished product.

Formulators using the product are responsible for obtaining EPA registration for their formulated product. Labeling for products formulated from this product must conform to that which is currently registered with the U.S. Environmental Protection Agency. For specific information on federally registered uses, contact Nufarm Americas Inc.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Keep container closed when not in use. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material is spilled for any reason or cause, carefully sweep material into a pile and dispose of as directed for pesticides below.

Refer to Precautionary Statements on label for hazards associated with the handling of this material. In spill or leak incidents, keep unauthorized people away. You may contact Chemtrec (800) 424-9300.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product maybe disposed of on site or at an approved waste disposal facility

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. For metal or plastic containers, triple rinse container (or equivalent) promptly after emptying. For fiber drums, completely empty the residue into manufacturing equipment. Then (for all containers), offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration if allowed by state or local authorities.

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300  
For Medical Emergencies Only, Call (877) 325-1840

#### WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A

**PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE.** UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

### **LIMITATION OF LIABILITY**

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BY WAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR ARISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

**If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.**

**(NEW)**

**8/3/2009 GLM**



# NOTE FOR RECORD

EPA Reg. No./ File Symbol: **35935-TT**

Product Name: **Fluroxypyr Technical (II)**

Original Application Dated: **August 3, 2009**

Due Date: **February 25, 2009**

Action Description: **New Technical Use Product** for several crop and non-crop use sites

Comments:

**PRODUCT CHEMISTRY:**

Basic CSF dated 08/03/09 was found acceptable by TRB

Product Chemistry data requirements for Group A and Group B are satisfied by MRID #s 47820901, 47820902, and 47820903.

The one year storage stability and corrosion characteristics are a data gap.

**ACUTE TOXICITY REVIEW:**

Signal Word: CAUTION

TRB found this product to be substantially similar to EPA Reg. No. 35935-53, thus the same acute tox. language was advised.

**DATA COMPENSATION:**

Data matrix with offer to pay for Cite-all option for generic and acute tox. data

**LABEL REVIEW:**

1. 2 minor changes to the Environment Hazards statement
2. 1 typo



DP BARCODE: D368329; FILE SYMBOL No.: 35935-TT; PRODUCT: Fluroxypyr Technical (II)

Date: January 26, 2010

**FEE**

SUBJECT: Product Chemistry Review of Fluroxypyr Technical (II) TGAI / MUP

FROM: Shyam B. Mathur, PhD  
Product Chemistry Team Leader  
Technical Review Branch/RD (7505P)

*S. B. Mathur*  
*01/26/10*  
*DM*

TO: Bethany Dalrymple / James Tompkins, RM 25  
Herbicide Branch / RD (7505P)

DP BARCODE: D368329  
DECISION No.: 418027  
File Symbol No.: 35935-TT  
PRODUCT: Fluroxypyr technical (II) TGAI / MUP  
PCC: 128968  
REGISTRANT: Nufarm Limited  
USE: Herbicide  
FOOD USE: Yes

INTRODUCTION:

The registrant Nufarm Limited has submitted a registration application for the new technical/mup product Fluroxypyr technical (II). The fluroxypyr technical (II) TGAI / MUP is produced by [REDACTED]

[REDACTED] In support of the application, the registrant has submitted 830 series group A and group B data with MRID Nos. 478209-01 thru 478209-03, a CSF for basic formulation (dated 08-03-09) and the product label. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 35935-53. TRB has been asked to evaluate the product chemistry data submitted and determine the similarity of the proposed product to the registered product.

SUMMARY OF FINDINGS:

1. The registrant has submitted a basic formulation CSF (dated 08-03-09) for fluroxypyr technical (II) TGAI /MUP. The average purity of the active ingredient in TGAI/MUP is 98.0%, as determined by the five batch analysis. The proposed certified limits for the AI and the impurities are based on the standard certified limits as set forth in 40CFR§158.350(b)(2). The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.320 and 158.350 respectively [MRID No. 478209-01].

2. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.325 [MRID No. 478209-01].

\*Product ingredient source information may be entitled to confidential treatment\*

**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.330. The manufacturing process for fluroxypyr technical (II) tgai / mup consists of [REDACTED]. The applicant has provided the details of the chemical process with reaction conditions, equipment used, working up procedures, and quality assurance steps [MRID No. 478209-01].
4. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.340. During the production of fluroxypyr technical (II) tgai/mup, the registrant discussed the formation of [REDACTED] impurities present at the concentration of >0.1% including [REDACTED]. No other impurities were reported during the 5 batch analysis. The registrant has stated that there is no possibility of the formation of impurities of toxicological concern as there are no preexisting conditions or starting materials present in the production process which are required for their formation [MRID No. 478209-01].
5. The data submitted corresponding the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements of 40CFR§158.345. The study was conducted under GLP requirements in compliance with 40CFR§160 and OECD requirements. The analysis study was performed by Eurofins/Product Safety Laboratories, Dayton, NJ, USA. Five representative batches of the fluroxypyr technical (II) tgai/mup were analyzed for percent active ingredient and the impurities. The active ingredient and the [REDACTED] impurities were identified and quantified by using HPLC-UV (225 nm) with external standard quantification method. The Karl Fisher titration method was used for the determination of the moisture content in the fluroxypyr tgai/mup. The LOD's & LOQ's for all the impurities were determined. The analytical methods were validated for accuracy, linearity, and precision [MRID Nos. 478209-02].
6. The data submitted corresponding the guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.355. The purity of the AI in the TGAI was determined by HPLC-UV by external standard method. The analytical method utilized Agilent Zorbax SB-C18 column, 250 mm x 4.6 mm, 5 µm particle size, with UV detector operating at 225 nm. The method was validated for precision, accuracy and linearity [MRID Nos. 478209-01].
7. The data submitted or cited corresponding to 830 series group B (physical-chemical properties) satisfy the data requirements of 40CFR§158.310 (e). One year studies corresponding to guidelines storage stability (830.6317) and corrosion characteristics (830.6320) are in progress [MRID No. 478209-03].

**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)

**CONCLUSIONS:**

The TRB has reviewed the product chemistry data submitted for fluroxypyr technical (II) TGAI/MUP [REDACTED] and has concluded that:

1. All the product chemistry data submitted & cited corresponding to the guidelines 830 Series group A and group B are acceptable, except for storage stability (830.6317) and corrosion characteristics (830.6320).
2. The proposed CSF for basic formulation (dated 08-03-09) is acceptable.
3. The registrant must conduct the one year storage stability (830.6317) and corrosion characteristics (830.6320) studies for the proposed fluroxypyr technical (II) tgai/mup under full GLP requirements. It is recommended that the observations should be made at the intervals of 0 (initial), 3 month, 6 month, 9 month, and 12 month (final). The results must be submitted to the Agency on completion.
4. The proposed product (File Symbol No. 35935-TT) was determined to be substantially similar to the registered product with Reg. No. 35935-53 from the product chemistry point of view.

\*Product ingredient source information may be entitled to confidential treatment\*



**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)

830.1550. Product identity & Composition: (MRID No. 478209-01)

CAS No.: 81406-37-3

Common name/alias: Fluroxypyr-meptyl

Chemical Names:

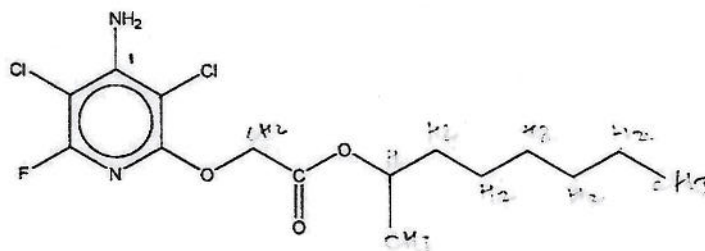
IUPAC: (RS)-1-methylheptyl 4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetate

CAS: 1-methylheptyl [(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate

Molecular formula:  $C_{15}H_{21}Cl_2FN_2O_3$  ✓

Molecular weight: 367.24

Structure:



\*Product ingredient source information may be entitled to confidential treatment\*

\*Manufacturing process information may be entitled to confidential treatment\*

**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)

Table 1. Manufacturing and Impurity Data for fluroxypyr technical II TGAI / MUP				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	Basic CSF (08-03-09)	A	The NC of AI (98.0%) is supported by 5 batch analysis & agrees with the label claim nominal concentration. [REDACTED] impurities are listed on the CSF including [REDACTED]
830.1600	Description of materials used to produce the product	478209-01	A	The description & composition for all the starting materials used to produce the fluroxypyr technical II ([REDACTED]) have been provided by the registrant
830.1620	Description of production process	478209-01	A	The AI was produced in [REDACTED] The production process has been described in full details.
830.1670	Discussion of formation of impurities	478209-01	A	The registrant has provided the complete mechanisms of formation, quantification and identification of all the impurities present in the product.
830.1700	Preliminary analysis	478209-02	A	Five representative batches fluroxypyr technical II [REDACTED] were analyzed for percent active ingredient and the impurities. The HPLC-UV (225 nm) method was used for the identification of the AI and the impurities. The five batch analysis supported the proposed CSF for basic formulation. The moisture contents were determined by Karl-Fischer titration method.
830.1750	Certified limits	478209-01	A	The proposed certified limits for the AI and impurities are based on standard certified limit table set-forth in 40CFR§158.350(b)(2).
830.1800	Enforcement analytical method	478209-01	A	The HPLC-UV (225 nm) with external standard method was used for the determination of the AI content in the TGAI/MUP. The method was validated for precision, linearity and accuracy.
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)				

DP BARCODE: D368329; FILE SYMBOL No.: 35935-TT; PRODUCT: Fluroxypyr Technical (II)

830 Series group B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of : Fluroxypyr technical II TGAI / MUP (China)				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	cited 475407-03	A	Off white
830.6303	Physical state	" " "	A	Solid
830.6304	Odor	" " "	A	Faint odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	" " "	A	Stable to Fe powder, iron acetate, Al powder and Al acetate at 54°C and at room temperature
830.6314	Oxidation/reduction: chemical incompatibility	478209-03	A	No reaction with water, Fe powder, Monoammonium phosphate, potassium permanganate & kerosene
830.6315	Flammability	Data matrix	W	Waiver request accepted
830.6316	Explosibility	" " "	W	Waiver request accepted
830.6317	Storage stability	" " "	I	1 year study in progress
830.6319	Miscibility		NA	
830.6320	Corrosion characteristics	Data Matrix	I	1 year study in progress
830.7000	pH (cited)	475407-03	A	3.30 at 25°C
830.7050	UV/Visible absorption (cited)	" " "	A	Acid: $\lambda = 210 \text{ nm}$ ; $\epsilon \text{ max} = 41010.1$ Base: $\lambda = 219 \text{ nm}$ ; $\epsilon \text{ max} = 23804.7$ Neutral: $\lambda = 210 \text{ nm}$ ; $\epsilon \text{ max} = 40673.4$
830.7100	Viscosity		NA	
830.7200	Melting point (cited)	475407-03	A	58.8°C
830.7220	Boiling point		NA	
830.7300	Density (cited)	475407-03	A	1.2455 g/ml @ 25°C
830.7370	Dissociation constants in water (DC) (cited)	" " "	A	No measurable DC could be determined in water
830.7550	Partition coefficient	478209-03	A	Log Po/w = 5.40
830.7840	Water solubility:	" " "	A	Water = 0.162 mg/l at 20°C; See Note 1 for organic solvents
830.7950	Vapor pressure (cited)*	" " "	A	$1.349 \times 10^{-3} \text{ mPa}$ at 20°C

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required); TBA = To Be Assigned

\* The pesticide Manual 11<sup>th</sup> Edition, British Crop Protection Council.



**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)

**Note1. 830.7840 (solubility) at 20°C:** (MRID No. 478209-03)

Methanol = 607.25 g/L; Dichloromethane = 969.56 g/L; Hexane = 69.40 g/L.

**830.1800. Enforcement of analytical method:** (MRID No. 478209-01)

The five batches of the fluroxypyr technical II were assayed by a validated analytical method based on HPLC employing an external standard technique using UV detector.

**Apparatus & parametrs**

Instrument: Agilent 1100 HPLC

HPLC column: Agilent Zorbax SB-C18, 250 mm x 4.6 mm, 5 µm

Column temperature: 30°C

Flow rate: 1.0 ml/min

Injection volume: 10 µl

UV detector wavelength: 225 nm

Retention time for Fluroxypyr-meptyl: approximately 17.9 minutes.

Mobile phase: A = water + trifluoroacetic acid adjusted to pH 3

B = acetonitrile

Time (min)	% A	% B
0	50	50
2	50	50
15	10	90
17	10	90
19	50	50
25	50	50

\*Confidential Statement of Formula may be entitled to confidential treatment\*

**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)

CONFIDENTIAL APPENDIX



\*Manufacturing process information may be entitled to confidential treatment\*

**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)

CONFIDENTIAL APPENDIX





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CONFIDENTIAL APPENDIX



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**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)

CONFIDENTIAL APPENDIX

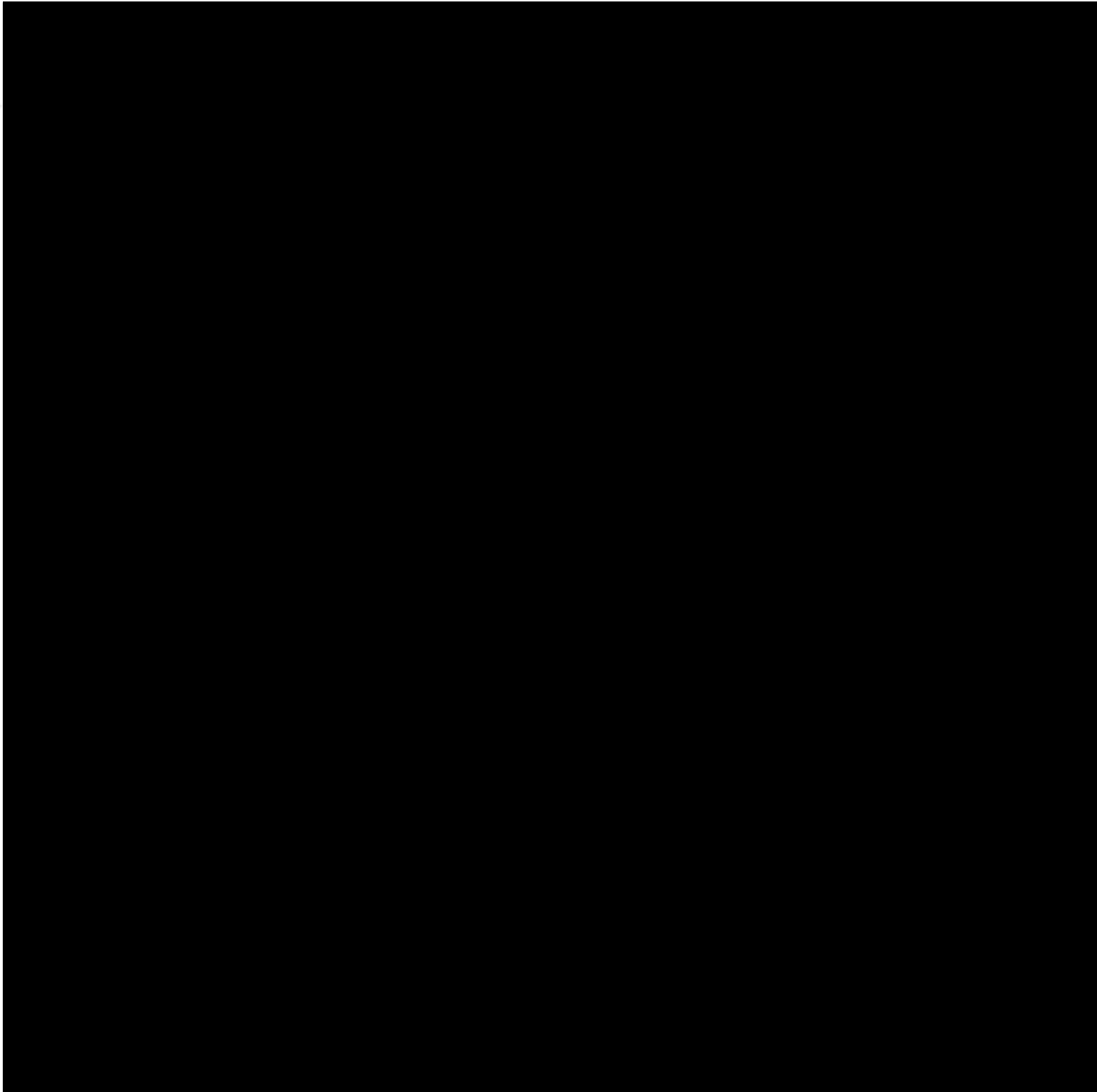




\*Manufacturing process information may be entitled to confidential treatment\*

**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)

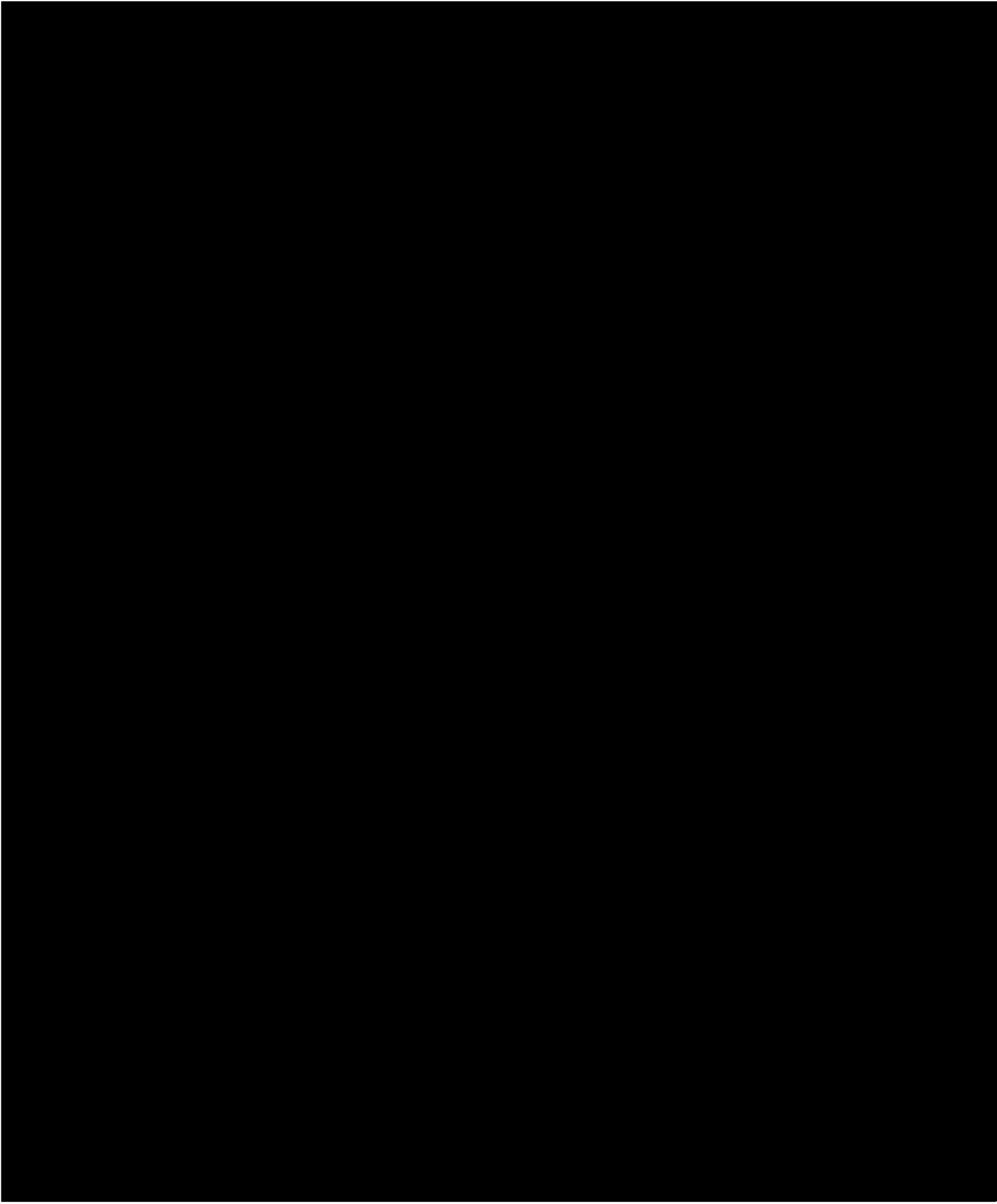
CONFIDENTIAL APPENDIX



CONFIDENTIAL APPENDIX

\*Manufacturing process information may be entitled to confidential treatment\*

**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)



**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)

CONFIDENTIAL APPENDIX

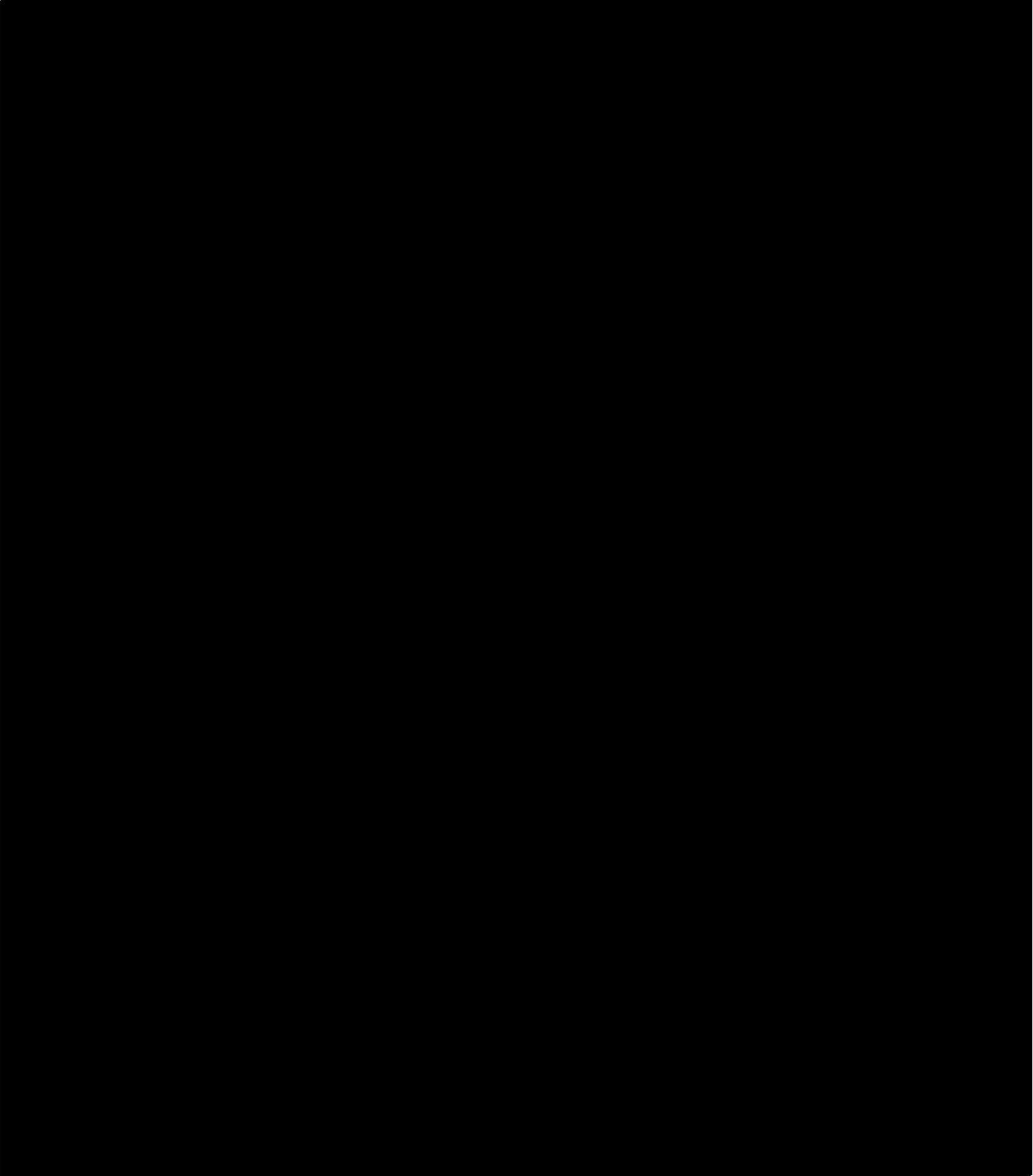


CONFIDENTIAL APPENDIX



\*Manufacturing process information may be entitled to confidential treatment\*

**DP BARCODE:** D368329; **FILE SYMBOL No.:** 35935-TT; **PRODUCT:** Fluroxypyr Technical (II)





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**TECHNICAL REVIEW BRANCH  
SIMILARITY CLINIC DETERMINATION**

13/JAN/2010

MEMORANDUM

Subject: Name of Pesticide Product: Fluroxypyr Technical (II)  
EPA Reg. No. /File Symbol: 35935-TT  
DP Barcode: 372905  
Decision No: 418027  
Action Code: R310  
PC Code: 128968 (fluroxypyr)

From: Masih Hashim, Toxicologist/Team Leader  
Technical Review Branch  
Registration Division (7505P)

*Handwritten signature and date:*  
B. T. Benbow  
1-14-2010

To: Bethany Benbow, RM Team 23  
Herbicide Branch  
Registration Division (7505P)

Applicant: Nufarm Limited  
150 Harvester Drive, Suite 200  
Burr Ridge, IL 60527

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Fluroxypyr	98.0
<u>Inert Ingredient(s):</u>	<u>2.0</u>
Total:	100.0

**ACTION REQUESTED:** To determine if the cited and proposed products are substantially similar (cite-all).

**RECOMMENDATIONS:**

TRB has evaluated the formulations of the proposed product, 35935-TT, and the cited product, 35935-53 and determined that the two products are substantially similar (cite-all as requested).

The proposed product should use the same precautionary labelling as the cited product. The Signal Word is CAUTION.

This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no further determination of the adequacy of the toxicological data base or the precautionary label of the cited product.

The proposed basic CSF should be accepted by Product Chemistry.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

August 7, 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

NUFARM LIMITED  
NUFARM LIMITED  
PO Box 13439  
RTP, NC 27709-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 04-AUG-09. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



Re: Fluroxypyr Technical (II) (EPA file symbol 35935-TT)   
Bethany Dalrymple to: George.Meindl

08/20/2009 07:27 AM

Mr. Meindl

Thank you for your timely response.

Beth Benbow, M.S.  
Biologist  
Herbicide Branch  
Registration Division  
U.S. Environmental Protection Agency  
office:(703) 347-8072  
email: Dalrymple.Bethany@epa.gov

George.Meindl

Dear Bethany - here is corrected EPA data matri...

08/19/2009 06:20:17 PM

From: George.Meindl@us.nufarm.com  
To: Bethany Dalrymple/DC/USEPA/US@EPA  
Date: 08/19/2009 06:20 PM  
Subject: Re: Fluroxypyr Technical (II) (EPA file symbol 35935-TT)

Dear Bethany - here is corrected EPA data matrix form.

(See attached file: 20090819 Fluroxypyr II Technical\_Agency Data Matrix revised prepared for Bethany.pdf)

Please acknowledgement receipt of this email and attachment.

Thank you for bring this to my attention and let me know if you have any further questions on this submission.

George Meindl  
Regulatory Affairs Manager  
Specialty Products Group  
Nufarm Americas Inc.  
150 Harvester Drive Suite 200  
Burr Ridge, IL 60527  
phone 630.455.2000 (main)  
phone 630.455.2017 (direct)  
fax 630.455.2030 (regulatory dept.)  
email george.meindl@us.nufarm.com

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Dalrymple.Bethany  
@epamail.epa.gov

08/19/2009 02:28  
PM

george.meindl@us.nufarm.com

To

cc

Subject

Fluroxypyr Technical (II)

Mr. Meindl

I am writing in regard to your submission in support of the application for registration of Fluroxypyr Technical (II). In reviewing the submitted data matrix, a few deficiencies were discovered.

- 1) The acute toxicity data requirements must be listed on the data matrix. Acute tox. does not fall under Generic Data Requirements.
- 2) The Generic Data Requirements list for offers to pay must include all the data submitters on the data matrix. The "xxx" is not sufficient.
- 3) The 4 task forces on page 4 should not have a status of "OWN." This should either be "PAY" or "MEM" (as a member of the task force).

Please send a revised pdf as an email attachment to me.

Thank you,

Beth Benbow, M.S.  
Biologist  
Herbicide Branch  
Registration Division  
U.S. Environmental Protection Agency  
office: (703) 347-8072  
email: Dalrymple.Bethany@epa.gov

\*\*\*\*\*  
\*

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Nufarm Americas Inc. and its affiliated companies. Fax: +1 630 455 2001.  
[attachment "20090819 Fluroxypyr II Technical\_Agency Data Matrix revised

prepared for . Bethany.pdf" deleted by Bethany Dalrymple/DC/USEPA/US]



# **FEE FOR SERVICE**

# Fee for Service

{855098R~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 23

Receipt No.

S-

855098

EPA File Symbol/Reg. No.

35935-TT

Pin-Punch Date:

8/4/2009

☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

R-310

Granted:

R-310

Amount Due: \$ 4578.00

## Parent/Child Decisions:

*Technical & impurities only - S. Rock 8/6/09*

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Venus Eagle

Date: 8/5/09

Remarks:

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 8-4-09<sup>3/23/09</sup>

Experts In-Processing Signature: B.R. Date 8-6-09

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>35935-TT</u>		EPA Receipt Date: <u>8-4-09</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		



7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			/
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			



**Comments:**

Passed 86-5 Review MRID 478209 -ID

\* N/A – Not Applicable

**Footnotes**

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;



3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



**Script for Rejection Phone calls**

**Contact Name:** George Meindl

**Phone #:** 630-455-2017

**Email:** george.meindl@us.nufarm.com

**First Call/Initials:**

**Date:** 8/10

**Time:** 3:05 PM

**Second Call/Initials:**

**Date:**

**Time:**

**This is** Jennifer Drabish, EPA contractor.

**I'm calling regarding your submission in support of**

Application for Registration of Fluoropyr Technical (11)

**We have found the following deficiencies regarding:**

**PR Notice 86.5: Yes or No**

**Volume/Study Title:**

**Volume/Study Title:**

**Volume/Study Title:**

**Additional volumes continued on back of page: Yes or No**

**Application Package:** Yes or No

Missing Certification (use selective method)

**These deficiencies have been approved by EPA.**

**The corrections can be faxed to 703-305-5060/Attn: \_\_\_\_\_.**

**Second Call/Email:**

**If we do not receive the corrections by \_\_\_\_\_, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.**



Re: Application for Registration of Fluroxpyr Technical (II)   
Jennifer Drobish to: George.Meindl

08/10/2009 03:34 PM

Mr Meindl

I just wanted to let you know that I have received your attachment. Thank you very much

Jennifer Drobish  
EPA Contractor  
703-305-1671

George.Meindl

Hello Jennifer - here is the signed EPA form 857...

08/10/2009 03:28:22 PM

From: George.Meindl@us.nufarm.com  
To: Jennifer Drobish/DC/USEPA/US@EPA  
Date: 08/10/2009 03:28 PM  
Subject: Re: Application for Registration of Fluroxpyr Technical (II)

Hello Jennifer - here is the signed EPA form 8570-34. I apologize for not including it with the original submission.

(See attached file: EPA form 8570-34 signed and emailed to Jennifer Drobish on 8.10.2009.pdf)

Please acknowledge receipt of this email. Let me know if you need anything else from me at this time.

Thank you,

George Meindl  
Regulatory Affairs Manager  
Specialty Products Group  
Nufarm Americas Inc.  
150 Harvester Drive Suite 200  
Burr Ridge, IL 60527  
phone 630.455.2000 (main)  
phone 630.455.2017 (direct)  
fax 630.455.2030 (regulatory dept.)  
email george.meindl@us.nufarm.com

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND EXEMPT FROM DISCLOSURE. If the reader of this message is not the intended recipient or an employee of agent responsible for delivering the message to the intended recipient you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please delete, destroy and in doing so do not save the message. Nufarm Americas, Inc. and its affiliated companies.

Drobish.Jennifer@  
epamail.epa.gov

08/10/2009 02:05  
PM

george.meindl@us.nufarm.com

To

cc

Subject  
Application for Registration of  
Fluroxpyr Technical (II)

Mr Meindl

This is Jennifer Drobish, EPA contractor. I am writing in regards to your submission in support of the application for registration of Fluroxpyr Technical (II). We have found a deficiency regarding the application package. The Certification with Respect to Citation of Data (EPA form 8570-34) is missing. Also, since the data matrix indicates that Nufarm owns data, please be sure to check the "selective method" on the Certification. This form can either be faxed to me at 703-305-5060/Attn: Jennifer Drobish or emailed to me at drobish.jennifer@epa.gov

Thank you  
Jennifer Drobish  
EPA Contractor  
703-305-1671

\*\*\*\*\*  
\*

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND EXEMPT FROM DISCLOSURE. If the reader of this message is not the intended recipient or an employee or agent responsible for delivering the message to this intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please delete, destroy, and do not save the message.

Nufarm Americas Inc. and its affiliated companies. Fax: +1 630 455 2001.  
[attachment "EPA form 8570-34 signed and emailed to Jennifer Drobish on 8.10.2009.pdf" deleted by Jennifer Drobish/DC/USEPA/US]





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

August 5, 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-418027  
EPA File Symbol or Registration Number: 35935-TT  
Product Name: FLUROXYPYR TECHNICAL (II)  
EPA Receipt Date: 04-Aug-2009  
EPA Company Number: 35935  
Company Name: NUFARM LIMITED

GEORGE MEINDL  
NUFARM LIMITED  
150 HARVESTER DRIVE, SUITE 200  
BURR RIDGE, IL 60527

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT  
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee  
Ombudsman at (703) 305-6249.

Sincerely,

A handwritten signature in cursive script that reads "Teresa Downs".

Front End Processing Staff  
Information Technology & Resources Management Division



## Online Payment

## Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

## Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 24VLR0B1

Agency Tracking ID: 74077536611

Transaction Date and Time: 08/03/2009 16:35 EDT

## Payment Summary

Address Information	Account Information	Payment Information
Account Holder Name: George Meindl 150 Harvester Billing Address: Drive Billing Address 2: Suite 200 City: Burr Ridge State / Province: IL Zip / Postal Code: 60527 Country: USA	Card Type: Master Card Card Number: *****1276 Decision Number: Registration Number:	Payment Amount: \$4,578.00 Transaction Date 08/03/2009 and Time: 16:35 EDT



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

		United States <b>Environmental Protection Agency</b> Washington, DC 20460		<input checked="" type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other</b>	OPP Identifier Number
<b>Application for Pesticide - Section I</b>					
1. Company/Product Number 35935- TT		2. EPA Product Manager Joanne Miller		3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Fluroxypyr Technical (II)		PM# 23			
5. Name and Address of Applicant (Include ZIP Code) Nufarm Limited 150 Harvester Drive Suite 200 Burr Ridge, IL 60527 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 62719-285/35935-53 Product Name Starane Technical/Fluroxypyr Technical			
<b>Section - II</b>					
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____			
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application.			
<input type="checkbox"/> Notification - Explain below.		<input checked="" type="checkbox"/> Other - Explain below.			
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.) R310 46, New manufacturing product registration request - substantially similar to a currently registered product \$4578.00 6 month review					
<b>Section - III</b>					
1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	
<b>Section - IV</b>					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name George Meindl (george.meindl@us.nufarm.com)		Title Regulatory Affairs Manager		Telephone No. (Include Area Code) 630.455. 2017	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Affairs Manager			
4. Typed Name George Meindl		5. Date 8/3/2009			





Nufarm Limited  
George Meindl  
Regulatory Affairs Manager  
150 Harvester Drive, Suite 200  
Burr Ridge, IL 60527  
Phone: 630.455.2017 Fax: 630.455.2030  
george.meindl@us.nufarm.com

August 3, 2009

Via Overnight Courier

Joanne Miller (PM-23)  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Subject: Fluroxypyr Technical (II)  
EPA Reg. No. 35935-  
Application for a New Product Registration  
Non-Fast track request R310 (46)

Dear Ms. Miller:

Nufarm Limited is interested in registering the subject product. Under the Pesticide Registration Improvement Act of 2007, it is our opinion that this action falls under PRIA category R310 46, (New manufacturing product), because it is an application for registration for a technical product substantially similar to a currently registered product. We are also using the cite-all method of support. As per EPA's interpretations of 40 CFR 152.86(b) (2) (i) and 152.93(b) (2) (i), Nufarm Limited submitted notices of intent to apply and offers to pay to all companies on the March 31, 2009 Data Submitter's List. Nufarm anticipates this action requires a fee of \$ 4,578 with a six -month review time at the Agency. We have prepaid the PRIA II fee, with copy of the pay.gov receipt included in this submission.

To process this request please find attached the transmittal document listing the administrative material and all the submitted studies needed to support this registration request.

Please note that the storage stability and corrosion characteristics are pending and will be submitted once completed.

If you should have any questions regarding this matter, feel free to contact me at 630.455.2017 or email at [george.meindl@us.nufarm.com](mailto:george.meindl@us.nufarm.com),

Thank you,

A handwritten signature in dark ink, appearing to read 'George Meindl', written over a horizontal line.

George Meindl  
Regulatory Affairs Manager  
Nufarm Limited



Nufarm Limited  
George Meindl  
Regulatory Affairs Manager  
150 Harvester Drive, Suite 200  
Burr Ridge, IL 60527  
Phone: 630.455.2017 Fax: 630.455.2030  
george.meindl@us.nufarm.com

August 3, 2009

Via Overnight Courier

Joanne Miller (PM-23)  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
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Thank you,

A handwritten signature in black ink, appearing to read 'George Meindl', written over a horizontal line.

George Meindl  
Regulatory Affairs Manager  
Nufarm Limited





**Nufarm Limited**  
**George Meindl**  
**Regulatory Affairs Manager**  
150 Harvester Drive, Suite 200  
Burr Ridge, IL 60527  
Phone: 630.455.2017 Fax: 630.455.2030  
george.meindl@us.nufarm.com

## TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Nufarm Limited  
150 Harvester Drive Suite 200  
Burr Ridge, IL 60527

2. Regulatory Action in Support of Which This Package is Submitted

Application for Pesticide Registration  
Fluroxypyr Technical (II)  
EPA File Symbol 35935  
PRIA category R310 46  
New Product/Non-fast track  
New Source of an existing active ingredient using "Cite all" method

3. Date of this Submission

August 3, 2009

4. List of Submitted Studies

### Administrative Documents

PRIA letter  
Application for Pesticide Registration (EPA form 8570-1)  
Confidential Statement of Formula (EPA form 8570-4)  
Certification with Respect to Citation of Data (EPA form 8570-34)  
Data Matrix (EPA form 8570-35) both public and EPA versions  
Proposed draft labels (5 copies)

Volume 1  
(3 copies of all studies)

**47820901** Product Chemistry (Guidelines 830.1550 - 1800)  
including the confidential attachment



**Nufarm Limited**  
George Meindl  
Regulatory Affairs Manager  
150 Harvester Drive, Suite 200  
Burr Ridge, IL 60527  
Phone: 630.455.2017 Fax: 630.455.2030  
george.meindl@us.nufarm.com

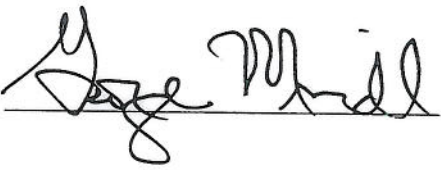
Volume 2  
(3 copies of all studies)

**47820902** Product Chemistry (Guidelines 830.1700)  
including the confidential attachment

Volume 3  
(3 copies of all studies)

**47820903** Oxidation/Reduction (Guideline 830.6314)  
Melting Point (Guideline 830.7200)  
Partition Coefficient (Guideline 830.7550/60/70)  
Water and Solvent Solubility (Guideline 830.7840/60)

Company Official: George Meindl

Signature: 

Company Name: Nufarm Limited

Company Contact: George Meindl Phone: 630.455.2017  
Registration Manager





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Nufarm Ltd. 104 T.W. Alexander Drive RTP, NC 27709 630.455.2017	EPA Registration Number/File Symbol 35935-TT
Active Ingredient(s) and/or representative test compound(s) fluroxypyr	Date 8/10/2009
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) terrestrial food/nonfood crop, forestry, greenhouse food/nonfood crop and nurseries, domestic outdoor	Product Name Fluroxypyr Technial (II)

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

8/10/2009

Typed or Printed Name and Title

George Meindl Regulatory Affairs Manager



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060

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**DATA MATRIX**

Date August 3, 2009

EPA Reg. No./File Symbol 35935-TT

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Applicant's/Registrant's Name & Address

Nufarm Limited  
 150 Harvester Drive, Suite 200  
 Burr Ridge, IL 60527

Product

Fluroxpyr Technical (11)

Ingredient Fluroxpyr

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Specific Data Requirements</b>					
830.1550	Product Identity and Composition	Volume 1	Nufarm Limited	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	Nufarm Limited	OWN	
830.1620	Description of Production Process	Volume 1	Nufarm Limited	OWN	
830.1650	Description of Formulation Process				
830.1670	Discussion of Formation of Impurities	Volume 1	Nufarm Limited	OWN	Not required <sup>1</sup>
830.1700	Preliminary Analysis	Volume 2	Nufarm Limited	OWN	
830.1750	Certified Limits	Volume 1	Nufarm Limited	OWN	
830.1800	Enforcement Analytical Method	Volume 1	Nufarm Limited	OWN	
830.6302	Color	47540703	Nufarm Limited	OWN	(see 35935-53)
830.6303	Physical State	47540703	Nufarm Limited	OWN	(see 35935-53)
830.6304	Odor	47540703	Nufarm Limited	OWN	(see 35935-53)
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	47540703	Nufarm Limited	OWN	(see 35935-53)
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 3	Nufarm Limited	OWN	
830.6315	Flammability		Nufarm Limited	OWN	
Signature			Name and Title		Date
			George Meinl, Regulatory Affairs Manager		8/3/2009




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**DATA MATRIX**

Date <b>August 3, 2009</b>	EPA Reg. No./File Symbol <b>35935-TT</b>	Page <b>2 of 5</b>
Applicant's/Registrant's Name & Address		
<b>Nufarm Limited</b> <b>150 Harvester Drive, Suite 200</b> <b>Burr Ridge, IL 60527</b>		
<b>Fluroxpyr Technical (II)</b>		


Ingredient <b>Fluroxpyr</b>	Guideline Study Name	MRLD Number	Submitter	Status	Note
830.6316	Explosibility		Nufarm Limited	OWN	Waiver <sup>3</sup>
830.6317	Storage Stability		Nufarm Limited	OWN	On-going
830.6319	Miscibility				Not required <sup>4</sup>
830.6320	Corrosion Characteristics		Nufarm Limited	OWN	On-going
830.6321	Dielectric Breakdown Voltage				Not required <sup>5</sup>
830.7000	pH	47540703	Nufarm Limited	OWN	(see 35935-53)
830.7050	UV/Visible Absorption	47540703	Nufarm Limited	OWN	(see 35935-53)
830.7100	Viscosity				Not required <sup>6</sup>
830.7200	Melting Point/Melting Range	Volume 3	Nufarm Limited	OWN	
830.7220	Boiling Point/Boiling Range				Not required <sup>7</sup>
830.7300	Density/Relative Density/Bulk Density	47540703	Nufarm Limited	OWN	(see 35935-53)
830.7370	Dissociation Constants in Water	47540703	Nufarm Limited	OWN	(see 35935-53)
830.7520	Particle Size, fiber length, and diameter distribution				Not required <sup>8</sup>
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	Volume 3	Nufarm Limited	OWN	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
Signature					
	Name and Title	George Meinl, Regulatory Affairs Manager			Date
					8/3/2009

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**DATA MATRIX**

Date August 3, 2009		EPA Reg. No./File Symbol 35935-TT	Page 3 of 5
Applicant's/Registrant's Name & Address  Nufarm Limited 150 Harvester Drive, Suite 200 Burr Ridge, IL 60527		Product  Fluroxypyr Technical (II)	
Ingredient Fluroxypyr			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography		
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	Volume 3	Nufarm Limited
830.7860	Water Solubility, Generator Column Method		
830.7950	Vapor Pressure	submitted	Nufarm Limited
870.1100	Acute Oral Toxicity: Rat	Cite-All	OWN (see 35935-53)
870.1200	Acute Dermal Toxicity: Rat	Cite-All	PAY
870.1300	Acute Inhalation Toxicity: Rat	Cite-All	PAY
870.2400	Primary Eye Irritation: Rabbit	Cite-All	PAY
870.2500	Primary Dermal Irritation	Cite-All	PAY
870.2600	Dermal Sensitization	Cite-All	PAY
Nufarm Limited will make offers-to-pay to the following companies on the March 31, 2009 Data Submitters List for Fluroxypyr			
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		Syngenta Crop Protection Inc. PAY
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		Loveland Products Inc. PAY
Signature  		Name and Title George Meindl, Regulatory Affairs Manager	
		Date 8/3/2009	




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**DATA MATRIX**

Date August 3, 2009		EPA Reg. No./File Symbol 35935-TT		Page 4 of 5	
Applicant's/Registrant's Name & Address		Product			
Nufarm Limited 150 Harvester Drive, Suite 200 Burr Ridge, IL 60527		Fluroxypyr Technical (II)			
<b>Ingredient Fluroxypyr</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		Albaugh Inc	PAY	
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		Dow Agrosciences LLC	PAY	
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		Lebanon Seaboard Corporation	PAY	
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		Helena Chemical Co.	PAY	
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		Arysta Life Sciences North America LLC	PAY	
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		Spray Drift Task Force	MEM	
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		Outdoor Residential Exposure Task Force	MEM	
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		Agricultural Reentry Task Force	MEM	
Fluroxypyr Generic Data Requirements	Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements		FIFRA Endangered Species Task Force LLC	MEM	
George Meindl, Regulatory Affairs Manager 			Date 8/3/2009		

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## DATA MATRIX

Date August 3, 2009

Applicant's/Registrant's Name &amp; Address

Nufarm Limited  
150 Harvester Drive, Suite 200  
Burr Ridge, IL 60527

EPA Reg. No./File Symbol	35935-TT
Product	

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Fluroxpyr Technical (II)

**Ingredient Fluroxypyr**

Guideline Reference Number

**Guideline Study Name**

MRID Number

### Submitter

## Fluroxypyr Generic Data

Cite-All utilized by Nufarm Limited for Fluroxypyr generic data requirements

## Agricultural Handlers Exposure Task Force

Status

### Note

**Signature**

Name and Title
George Meindl, Regulatory Affairs Manager

Date  
8/3/2009

\*Confidential Statement of Formula may be entitled to confidential treatment\*